

**CRITERIA FOR PRIOR AUTHORIZATION**

Zinplava® (bezlotoxumab)

**PROVIDER GROUP:** Pharmacy

**MANUAL GUIDELINES:** The following drug(s) requires prior authorization:  
Bezlotoxumab (Zinplava®)

**CRITERIA FOR PRIOR AUTHORIZATION** (must meet all of the following):

- Patient must have diagnosis of *Clostridium difficile* infection (CDI) confirmed by documentation of positive toxin B *Clostridium difficile* test, or that the facility is unable to test for toxins (would only require a positive CDI)
- Patient will receive or is currently receiving concomitant antibacterial drug treatment for CDI (e.g. metronidazole, vancomycin, fidaxomicin)
- Patient has had at least two episodes of CDI recurrence (3 episodes) in the previous 6 months and has been treated with appropriate treatment for CDI\*, including a pulsed vancomycin regimen
- Dosing frequency must not exceed 1 dose

**APPROVAL LENGTH:** 1 dose

**Notes:**

- Recurrent episodes of CDI are treated with metronidazole, vancomycin, or fidaxomicin. The first recurrence should be treated with the same treatment as the initial episode. The second recurrence should be treated with vancomycin in a pulsed regimen and the third recurrence with a pulsed regimen and consideration for fecal microbiota transplant.
  - Metronidazole: 500 mg orally 3 times per day for 10 - 14 days
  - Vancomycin: 125 mg orally 4 times per day for 10 days
  - Fidaxomicin: 200 mg orally twice daily for 10 days
  - Pulsed Vancomycin: 10 days course of vancomycin at 125 mg four times per day, followed 125 mg daily pulsed every 3 days for 10 doses
- Repeat dosing is not recommended

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Drug Utilization Review Committee Director

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Pharmacy Program Manager,  
Division of Health Care Finance  
Kansas Department of Health and Environment

Date \_\_\_\_\_

Date \_\_\_\_\_